

abundant bust through hydrotherapy; and 502(f) (1)—the labeling failed to bear adequate directions for use for the purposes for which it was intended, namely, for use on the female breast.

DISPOSITION: 2-26-62. Default—20 devices and display cases and accompanying labeling were delivered to the Food and Drug Administration; remainder destroyed.

7029. Affinitizer device. (F.D.C. No. 45524. S. No. 68-735 R.)

QUANTITY: 1 device at Dallas, Tex., in possession of Mrs. Yuba G. Freeman, naturopath.

SHIPPED: Sometime during 1952, from Glendale, Calif.

LABEL IN PART: (Embossed on device) "Affinitizer."

ACCOMPANYING LABELING: Booklet entitled "The Diagonometer Seroyal Brands, Inc., Orinda, California."

RESULTS OF INVESTIGATION: The inspector's photographs and description indicated the article to be in the form of a hollow plastic block, about 12 inches square and 1 inch thick. On the face of the block is an indicator dial with inscribed numbers ranging from 0 to 270. The unit contains no electrical circuit, but the dial operation is reportedly magnetic. Three plastic strings are taped to the plastic block. For diagnostic purposes, one string is held over the area of the patient's heart, one string is placed in the area of the gland or organ to be checked, and one string is held over the dial of the device.

LIBELED: 3-24-62; amended libel 4-26-61, N. Dist. Tex.

CHARGE: 502(b) (1)—while held for sale, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(f) (1)—its labeling failed to bear adequate directions for the purposes for which it was intended, namely, in the treatment of diabetes, and in the diagnosing of the condition of the pituitary, liver, thyroid, and pancreas glands, the purposes for which the article was used by Mrs. Freeman; and 502(a)—when shipped and while held for sale, the labeling accompanying the article, contained false and misleading representations that the article was adequate and effective for diagnosing practically all diseases and conditions including, but not limited to, the following diseases and conditions; pneumonia, tuberculosis, diphtheria, cancer, malaria, syphilis, trichina, meningitis, tapeworm, fibroid tumor, anthrax, kidney stone, gallstone, polio, colitis, tularemia, blood sugar, bronchitis, asthma, rheumatic fever, gastric ulcer, botulism, sinusitis, nephritis, psoriasis, infectious mononucleosis, Vincent's angina, Banti's disease, filariasis, tetanus, hay fever, eczema squamosum, eczema madidans, cirrhosis of the liver, influenza, smallpox, impetigo; and that the article was adequate and effective for (a) determining where spinal adjustments were needed; (b) determining the locations of adhesions in the abdomen; (c) determining whether food contains poison; (d) determining whether the subject's heart and bloodstream are in a normal or subnormal condition; (e) determining the acid-alkaline balance of the body; (f) pointing out the foods which increase vitality in the body and foods which decrease vitality; and (g) pointing out the organs that have succumbed to toxicity and the nature and extent of the disease.

DISPOSITION: Mrs. Yuba G. Freeman filed a plea of intervention and, thereafter, the Government filed interrogatories, which were answered by the intervenor. The Government then filed a motion for summary judgment based on the answers to interrogatories. On 2-24-62, the court entered an order granting the motion for summary judgment, condemning the article, and providing for delivery of the device to the Food and Drug Administration.

DRUG FOR VETERINARY USE

7030. Turkey Formula Streppenmycin. (F.D.C. No. 46156. S. No. 54-595 R.)

QUANTITY: 1 keg containing 18 unlabeled 5-lb. bags at Lone Rock, Wis.

SHIPPED: 5-24-61, from Mankato, Minn., by Paul's Products Co.

LABEL IN PART: (Keg) "Turkey Formula 100 pounds 20/5# bags * * * Streppenmycin * * * As an aid in the control of Streptomycin and Penicillin sensitive bacteria usually present in infectious sinusitis, air sac, or blue comb disease in turkeys. Each pound contains * * * manufactured by Paul's Products Co. Mankato, Minnesota Directions * * * Control No. 213 Exp. Date Sep. 1963."

LIBELED: 8-2-61, W. Dist. Wis.

CHARGE: 502(b)—when shipped and while held for sale, the article failed to bear a label (bag) containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of quantity of contents; 502(e) (2)—its label failed to bear the common or usual name of each active ingredient; and 502(f) (1)—the labeling failed to bear adequate directions for use.

DISPOSITION: 3-17-62. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICES FOR HUMAN USE*

7031. Calcium lactate tablets. (F.D.C. No. 47224. S. No. 24-407 T.)

QUANTITY: 4 25,000-tablet drums and 1 20,000-tablet drum at Cleveland, Ohio.

SHIPPED: 12-6-61, from Worcester, Mass.

RESULTS OF INVESTIGATION: Examination showed the presence of moldy tablets.

LIBELED: 3-8-62, N. Dist. Ohio.

CHARGE: 501(b)—while held for sale, the article purported to be and was represented as *calcium lactate tablets*, a drug, the name of which is recognized in the National Formulary, an official compendium, and its quality or purity fell below the standard set forth in such compendium by reason of the presence therein of moldy tablets.

DISPOSITION: 4-25-62. Default—destruction.

7032. Trisulfacidin suspension. (F.D.C. No. 47172. S. No. 38-556 T.)

QUANTITY: 8 1-gal. btls. at Birmingham, Ala.

SHIPPED: 11-17-61, from St. Louis, Mo., by Organo Pharmaceutical Co.

LABEL IN PART: (Btl.) "Cyclonized Trisulfacidin Suspension * * * Each Teaspoon (5 cc.) contains: Sulfadiazine 0.166 Gm. Sulfamerazine 0.166 Gm. Sulfamethazine 0.166 Gm. Pyrilamine Maleate 6.25 mg. Pheniramine Male-

*See also No. 7005.